

DETAILED ACTION

Claims 1-18 are pending in instant application: 10590601

Summary of Invention Claimed

1. A carrier system in the form of avidin-modified protein-based nanoparticles to which biotinylated antibodies are bound by forming a stable avidin-biotin complex.

Election of Claims

2. Applicants' election with traverse of Group I (claims 1-5, 15, and 16) in the reply filed on 07/27/2009 is acknowledged. Applicants' did not state a reason for election with traverse. Thus, the restriction requirement is still deemed proper and is therefore made FINAL.

Claims 6, 7-14, 17 and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups II-III, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 07/27/2009.

Foreign Priority

3. Application 10590601, filed 08/24/2006 is a national stage entry of PCT/EP05/02185, International Filing Date: 03/02/2005 claims foreign priority to 102004011776.4, filed 03/09/2004.

Foreign priority application 102004011776.4, filed 03/09/2004 is within one year and applicant claimed priority to it in the declaration of instant application, so applicants' claim under 35 USC 119(a)-(d) to obtain the benefit of foreign priority is acknowledged.

**Claim Rejections - 35 USC § 102**

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Instant claims 1-5, 15 and 16 are rejected under 35 U.S.C. 102(b) as anticipated by Kreuter et al (WO 02089776 (German:English Translation); published 14 November 2002).**

Regarding claims 1-5, Kreuter teaches nanoparticles made from proteins with coupled apolipoprotein E. Furthermore, the Kreuter reference teaches nanoparticles based on human serum albumin, to which apolipoprotein E is coupled covalently or by using an avidin-biotin complex to enable the crossing of the blood barrier in order to transport pharmaceutical or biological active agents to target the cerebrospinalis (p.1, paragraph 1; p.18, Fig. 1 Deutsche WO 02089776). The nanoparticles can have one or more functional proteins bound by the way of bifunctional spacer molecules to thiol groups of the thiol group-modified nanoparticles. The thiol group-modified nanoparticles are prepared by converting the functional groups located on the surface of the protein nanoparticles (amino groups, carboxyl groups, hydroxyl groups) to be converted by suitable reagents to form surface reactive thiol (-SH) groups. Furthermore, functional proteins can then be bound to the thiol group-modified nanoparticles via the bifunctional spacer molecules that can react with both amino groups, as well as the free thiol groups (p.1, paragraph 12). Moreover, functional proteins that are coupled to the modified nanoparticles may be selected from the group comprising avidin, avidin derivatives, apolipoproteins such as apolipoprotein E, but also included is antibodies, enzymes, and the like. As such, the functional proteins

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themselves can pharmacological or biological action (p.2, paragraph 1, claim 4). The Kreuter reference teaches modified nanoparticles covalently coupled with avidin, where biotinylated apolipoprotein E can be bound (illustrated in p.18, Fig. 1 Deutsche WO 02089776). A carrier made from the protein thiol modified nanoparticles, bifunctional spacer, avidin, and biotinylated antibodies can also be prepared. Kreuter teaches that the carrier made from the protein nanoparticles may have pharmacologically or biologically active substances. These active substances may be incorporated in the nanoparticles, or they can be bound to the nanoparticles. Also, the binding of the pharmacologically or biologically active agents may be performed covalently with a complex-formation via the avidin-biotin system (p.3, second paragraph).

Regarding claims 15 and 16, Kreuter teaches that gelatine A, gelatine B, casein or comparable proteins are suitable as starting proteins to make the nanoparticles (p.1, paragraph 10). Moreover, the Kreuter reference teaches nanoparticles based on human serum albumin, to which apolipoprotein E is coupled covalently or using an avidin-biotin connection to enable the crossing of the blood barrier (p.1, paragraph 1; p.18, Fig. 1 Deutsche WO 02089776).

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Therefore, claims 1-5, 15 and 16 are anticipated from the teachings of Kreuter.

#### Conclusions

Claims 1-5, 15, and 16 are rejected.

#### 5. Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thurman Wheeler whose telephone number is (571)270-1307. The examiner can normally be reached on Monday-Thursday, 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/  
Primary Examiner, Art Unit 1651